

***Remarks***

This Amendment is in response to the Office Action dated **May 14, 2007**.

Applicants have canceled claims 1-26 and 39-62 without prejudice as being drawn to a non-elected invention. Applicants reserve the right to prosecute these claims in a divisional application.

Applicants have added new claims 63-68 that are directed to an expandable medical balloon. Support for claims 63-64 can be found at least from FIG. 10 and the description thereof found on page 17, lines 21-31. Support for claims 65-68 can be found at least from FIGS. 11A-11C and the corresponding description thereof found on page 17, lines 32-33 and page 18, lines 1-20 no new matter has been added. These claims are patentably distinguishable from the art of record.

***Claim Objections***

Claims 28-31 and 33-38 have been objected to. The examiner requests that Applicants write out all claim limitations and clarify the claimed subject material with regards to the product by process claims.

Applicants have amended claims 30 and 31 to clarify their dependency. However, the remaining claims are dependent from claims 28 and 33, and as such, are correctly written. Claim 28 describes a process of making the balloon of claim 27. Claim 27 is patentably distinct over the art of record as discussed below. Therefore, claim 28, a product-by-process claim, is also patentably distinct over the art of record.

Applicants respectfully request withdrawal of the objection to claims 28-31 and 33-38.

*Rejections*

*35 U.S.C. §102(b)*

**Crocker et al., US 6,120,523**

Claims 27-29 and 32-37 have been rejected under 35 U.S.C. §102(b) as being anticipated by Crocker et al. (6,120,523). It is asserted in the Office Action that Crocker et al. disclose a focalized intraluminal balloon.

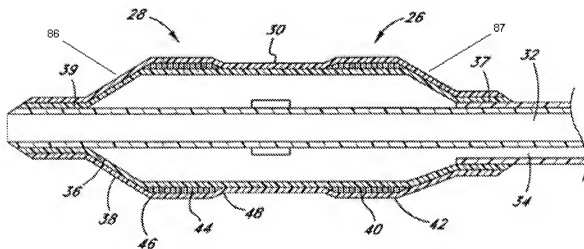
Applicants traverse the rejection.

Applicants submit that claim 27 of the present application is directed to an embodiment wherein the balloon has a central body wall portion between each end spaced apart from the balloon ends and connected thereto by means of tapering proximal and distal wall portions, respectively, wherein the balloon further comprises a lumen extending longitudinally therethrough, said lumen passing through the proximal and distal wall portions of the balloon.

In making the rejection of claim 27, it is asserted in the office action that the balloon disclosed by Crocker et al. “....comprises a lumen (32) extending longitudinally therethrough, said lumen passing through the proximal and distal wall portions of the balloon (Figures 1-4).” Office Action, page 4, top.

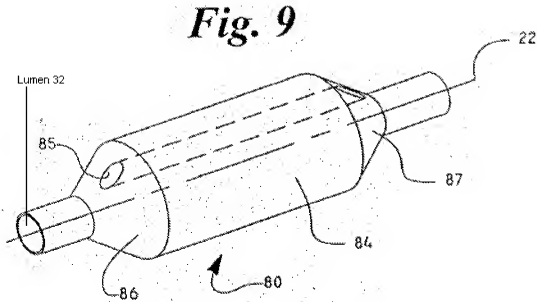
Applicants disagree.

Applicants have reproduced FIG. 2 from Crocker et al. below in order to illustrate the position of lumen (32).

**FIG. 2**

Applicants submit that, contrary to what is asserted in the Office Action, the lumen (32) disclosed in the Crocker et al. reference and shown in FIG. 2, above, is not the same as the lumen that extends longitudinally through the balloon wall as recited in Applicants' claim 27 and which emerges through the proximal and distal wall sections. Applicants have added reference numerals 86, 87 to the Crocker et al. reference to illustrate the positions on the balloon through which the lumen recited in claim 27 passes through. Clearly, from FIG. 2, it can be understood that the lumen recited in Applicants' claim 27 is not the same as lumen 32 of the Crocker et al. balloon.

Applicants have also reproduced FIG. 9 from the present specification below to further clarify the position of the lumen recited in claim 27 versus that of lumen (32) in the Crocker et al. balloon. Please also refer to page 16, lines 11-16 of the present specification for the description of FIG. 9.



Applicants have added reference numeral 32 to FIG. 9 to illustrate where a similar lumen to that shown in FIG. 2 of Crocker et al. would be located in Applicants' balloon. Clearly, lumen 85 of the present application is not the same as lumen 32 of the Crocker et al. balloon as asserted in the Office Action.

Therefore, Applicants submit that the rejection under 35 U.S.C. §102(b), which requires that the prior art reference disclose all of the features as arranged in Applicants' claim, cannot be maintained because the Crocker et al. reference fails to disclose a lumen as recited in independent claim 27. "Anticipation" means that the claimed invention was previously known, and that all of the elements and limitations of the claim are described in a single prior art reference." *Hakim v. Cannon Avent Group PLC*, 81 USPQ2d 1900, 1905 (Fed. Cir. 2007) (referring to *Akzo N.V. v. U.S. Int'l Trade Comm'n*, 808 F.2d 1471, 1479 [1 USPQ2d 1241] (Fed. Cir. 1986) ("Under 35 U.S.C. §102, anticipation requires that each and every element of the claimed invention be disclosed in a prior art reference.")). See also *MPEP* 2131 (referring to *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990); *In re Schreiber*, 128 F.3d 1473,

1477, 44 U.S.P.Q.2d (BNA) 1429, 1431 (Fed. Cir. 1997); and *Glaxo Inc. v. Novopharm Ltd.*, 52 F.3d 1043, 1047, 34 U.S.P.Q.2d (BNA) 1565, 1567 (Fed. Cir. 1995).

Claims 28-31 depend from claim 27 and are not anticipated by Crocker et al. for at least the reasons that claim 27 is not anticipated by Crocker et al.

Claim 32 is directed to an embodiment of an article including a multi-layer polymeric material film including at least first and second layers. The first and second layers are in adherent contact with each other over a coextensive area along respective outer and inner surfaces. Each of the first and second layers has an at-rest configuration defining an at-rest area on the respective outer and inner surfaces corresponding to the coextensive area. *The at-rest area of the first layer outer surface being smaller than the at-rest area of the second layer inner surface.*

In other words the interface surface is stressed due to the at-rest area of the first layer outer surface being smaller than the at-rest area of the second layer inner surface. The at-rest recitation assures that the interface stress is maintained even when no outside stress (such as balloon inflation) is applied.

In rejecting claim 32, it is asserted in the Office Action that:

Crocker et al. discloses a polymeric balloon that is capable of being radiation cured and is capable of being made of a fluidizable polymer composition, that is comprises of a multi-layer polymeric film (39, 36, 38, 40, 42, 44) wherein a first (39, 48) and second layers are in adherent contact over a coplanar coextensive region defining an at rest and open configuration resulting in a change of surface area (Figures 2-3), with a layer comprising an elastomeric band (40, 44) that is stretched during the configuration change.

Applicants disagree. There is nothing in the disclosure of Crocker et al. to suggest that the bands 40, 44 are elastomeric. In fact, with respect to Figures 2 and 3, Crocker et al. disclose that the bands are polyester. See col. 5, lines 36-40. Crocker et al. also disclose other "...nondistensible materials such as nylon, polyamide, Kevlar fiber, cross-linked polyethylene, polyethylene terephthalate and others may be utilized to accomplish the expansion limiting effect." Col. 5, lines 40-43.

As known to those of skill in the art, these nondistensible materials are not elastomeric, and there is nothing in the disclosure of Crocker et al. to suggest that the bands 40, 44 disclosed therein are elastomeric. In fact, non-distensibility implies that the materials are not readily stretchable as elastomeric materials obviously are.

Furthermore, Crocker et al. fail to disclose that the at-rest area of the outer surface of the bands is smaller than the at-rest area of the corresponding inner surface of the outer balloon 38 disclosed therein, as recited in claim 32. Crocker's bands are not stretched as assembled on the balloon. Consequently the at-rest areas on both interface surfaces should be equal.

Claim 32 is therefore not anticipated by Crocker et al. at least because Crocker et al. fail to disclose bands that have an outer surface area that has a smaller at-rest area than the corresponding inner surface of outer balloon 38 as required by Applicants' claim 32. Therefore, the reference fails to disclose all of the elements recited in claim 32 as required by 35 U.S.C. §102(b).

Claims 33-38 depend from claim 32 and are not anticipated by Crocker et al. for at least the reasons that claim 32 is not anticipated by Crocker et al.

Applicants respectfully request withdrawal of the rejection of claims 27-29 and 32-37 have been rejected under 35 U.S.C. §102(b) as being anticipated by Crocker et al. (6,120,523).

**Hamlin, US 6,132,824**

Claims 27-29, 32-35 and 38 have been rejected under 35 U.S.C. §102(b) as being anticipated by Hamlin (6,132,824). It is asserted in the Office Action that “...the balloon further comprises a lumen (52) extending longitudinally there through, said lumen passing through the proximal and distal wall portions of the balloon (Figures 5-6).”

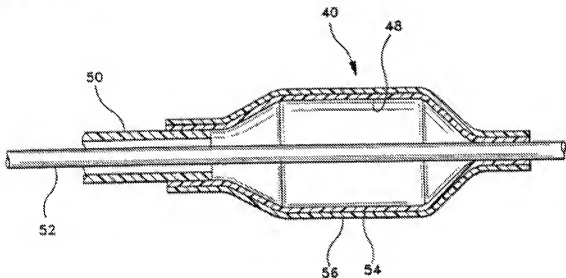
Applicants traverse the rejection.

Claim 27 has been discussed above and has a lumen extending longitudinally through the central body portion and passing through the proximal and distal wall portions of the balloon. See lumen 85 of FIG. 9, reproduced above, as an example.

The lumen recited in claim 27 is not the same as lumen 52 shown in FIGS. 5-6 of Hamlin as asserted in the Office Action.

Applicants have reproduced FIG. 5 of Hamlin below for illustration (FIG.6 illustrates a similar lumen 52):

FIG-5



Lumen 52 is actually referred to by Hamlin as an inner tubular body 52. See col. 5 of Hamlin. It is quite clear from FIG. 5, above, and from the corresponding description thereof, that inner tubular body 52 does not extend longitudinally through the central body wall of the balloon and does not pass through the proximal and distal wall portions as recited in independent claim 27 of the present application. In fact, inner tubular body 52, shown in FIG. 5 above, is a tubular member that is separate from the balloon and one to which the balloon is actually bonded:

When it is desired to bond the finished balloon onto the catheter body as illustrated in FIG. 5, the inner layer 48 of PVC can readily be bonded to an outer PVC tubular body 50 and to an inner tubular body 52, such as by adding adhesive 54 between the outer layer 56 and the inner layer 48. The space between the coaxially disposed tubes allows for injection of a balloon inflation fluid. Balloons produced in accordance with the invention may exhibit a burst pressure well in excess of 7 atmospheres while radially expanding less than about 3-10 percent. While the PVC layer 48 adds little to the burst strength of the composite, it does facilitate the attachment of the balloon to the exterior of the tubular catheter body.



Inner tubular member 52 shown in FIG. 5 of Hamlin, would actually be found at position 22 in FIG. 9 of the present application wherein the balloon longitudinal axis is shown, and not where lumen 85 is shown. Please refer to FIG. 9 above.

Claim 27 is not anticipated by Hamlin because the inner tubular body 52 shown in FIG. 5 of Hamlin, is not the same as the lumen recited in claim 27, and therefore all of the features of the instant claim are not disclosed by Hamlin as required by 35 U.S.C. §102(b).

Claims 28 and 29 depend from claim 27 and are not anticipated by Hamlin for at least the reasons that claim 27 is not anticipated by Hamlin.

Claim 32 has been discussed above. Claim 32 is to an embodiment of an article including a multi-layer polymeric material film including at least first and second layers. The first and second layers are in adherent contact with each other over a coextensive area along respective outer and inner surfaces. Each of the first and second layers has an at-rest configuration defining an at-rest area on the respective outer and inner surfaces, *the at-rest area of the first layer outer surface being smaller than the at-rest area of the second layer inner surface.*

It is asserted in the Office Action that:

Hamlin discloses a polymeric balloon that is capable of being radiation cured and is capable of being made of a fluidizable polymer composition, that is comprised of a multi-layer polymeric film (64, 66, 68) wherein a first (64, 66) and second layers are in adherent contact over a coplanar coextensive region defining an at rest and open configuration resulting in a change of surface area (Figures 5-6)

Office Action, page 5, top.

The inner layer 48 and the outer layer 56 shown in FIG. 5 and layers 60, 62 and 64 shown in FIG. 6 are all completely coextensive with one another. Adhesive 66, 68 may be

juxtaposed between the layers. See col. 5, lines 50-61. As formed, the layers are not stressed relative to each other so the at-rest areas of the coextensive areas of the layers are not different from each other.

Applicants respectfully request withdrawal of the rejection of claims 27-29, 32-35 and 38 under 35 U.S.C. §102(b) as being anticipated by Hamlin (6,132,824).

***35 U.S.C. §103(a)***

Claims 30-31 have been rejected under 35 U.S.C. §103(a) as being obvious over Crocker et al. It is asserted in the Office Action that “Crocker et al. meets the claim limitations as described above except for the specific embodiment being used in with a stent or with a rapid exchange catheter. Regarding claims 30-31, Crocker et al. teaches a specific medical balloon structure that is disclosed of being used with a rapid exchange and for delivery of stents to the vascular system (col. 3, ln 40-70, col. 5, ln 40-70, see summary of the invention).” Office Action, page 5, last two paragraphs.

Applicants traverse the rejection.

Claims 30-31 depend from claim 27.

As shown above, lumen (32) disclosed by Crocker et al. is different than the lumen recited in claim 27 that extends longitudinally in the central body wall and passes through the proximal and distal end walls of the balloon as recited in claim 27. Please refer to FIG. 9 of the present application, reproduced above, illustrating lumen (85) in the balloon wall as compared to lumen (32) shown in FIG. 2 of Crocker et al., also reproduced above.

Crocker et al. fails to disclose a balloon having a lumen of the type recited in claim 27. Combining a rapid exchange catheter or a stent with the balloon disclosed by Crocker et al.

does not render claim 27 obvious over Crocker et al. Furthermore, the balloon structure recited in claim 27 is not a predictable variation of the Crocker et al. balloon. As disclosed on page 16 of the present application, the design of having the lumen extending longitudinally in the balloon wall provides a pressure chamber that completely surrounds the guide wire channel such that the pressure on the guide wire channel is equally exerted from all directions and the guide wire is not forced against the wall of the balloon during inflation. See page 16, lines 9-19 of the present application. However, the disclosure of Crocker et al. does not provide any foreseeable benefit to moving the central guide wire port, i.e. lumen (32), disclosed therein for such a purpose. If one of skill in the art cannot implement a predictable variation, or see the benefit of doing so, the reference does not preclude patentability under 35 U.S.C. §103(a). See *KSR International v. Teleflex Inc.*, U.S. Supreme Court No. 04-1350 (April 30, 2007).

**CONCLUSION**

Claims 27-38 and 63-68 are pending in the application. Applicants have addressed each of the issues presented in the Office Action. Based on the foregoing, Applicants respectfully request reconsideration and an early allowance of the claims as presented. Should any issues remain, the attorney of record may be reached at (952)563-3011 to expedite prosecution of this application.

Respectfully submitted,  
VIDAS, ARRETT & STEINKRAUS

Date: August 2, 2007

By: /Lisa Ryan-Lindquist/  
Lisa Ryan-Lindquist  
Registration No.: 43,071

6640 Shady Oak Dr., Suite 400  
Eden Prairie, MN 55344-7834  
Telephone: (952) 563-3000  
Facsimile: (952) 563-3001

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